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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,436	08/17/2006	Sarah Kingsland	FDEHN7.002APC	5916

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EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

NOTIFICATION DATE	DELIVERY MODE
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06/11/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/520,436	Applicant(s) KINGSLAND ET AL.	
	Examiner PHUONG HUYNH	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,11,16-20 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) 16-20, 22 and is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 11 and 24-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/16/09</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1, 3-5, 11, 16-20 and 22-27 are pending.
2. Claims 16-20, 22 and 23 stand withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.
3. Claims 1, 3-5, 11 and 24-27, drawn to a method for separation and purification of fibrinogen and plasminogen and fibrinogen prepared by said process, are being acted upon in this Office Action.
4. The rejection of claims 1-7, 11 and 24-27 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01 has been obviated by the claims amendment filed March 16, 2009.
5. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by US Pat No. 5,169,936 (issued Dec 8, 1992; PTO 1449) has been obviated by the claims amendment filed March 16, 2009.
6. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Hari et al (J Biomed Mater Res 50: 110-113, 2000; PTO 892) has been obviated by the claims amendment filed March 16, 2009.
7. The rejection of claims 1-7, 11 and 24-26 under 35 U.S.C. 103(a) as being unpatentable over WO 95/25748 (published Sept 1995; PTO 1449) in view of Hari et al (J Biomed Mater Res 50: 110-113, 2000; PTO 1449) and Chaga et al (J Biochem Biophys Methods 49: 313-334, 2001; PTO 892) has been obviated by the claims amendment filed March 16, 2009.
8. The rejection of claim 27 under 35 U.S.C. 103(a) as being unpatentable over WO 95/25748 publication (published Sept 1995; PTO 1449) in view of Hari et al (J Biomed Mater Res 50: 110-113, 2000; PTO 1449) and Chaga et al (J Biochem Biophys Methods 49: 313-334, 2001; PTO 892) as applied to claims 1-7, 11 and 24-26 mentioned above and further in view of WO

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96/17631 publication (published June 1996; PTO 1449) has been obviated by the claims amendment filed March 16, 2009.

9. The following new grounds of rejection are necessitated by the amendment filed March 16, 2009.
10. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
11. Claims 1, 3-5 and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the buffer conditions such as greater than 20 mM arginine, lysine or imidazole, 10 mM trisodium citrate, 50 mM NaCl and pH 7.5 that selectively eluting the fibrinogen off the column and the condition i.e., less than or equal to 20 mM alanine or leucine, less than 10 mM lysine or imidazole, 20 mM Na₂HPO₄, 0.5 M NaCl and pH 7.5 to elute bound plasminogen separately off the metal ion such as copper or zinc affinity chromatography matrix are missing in the claims, see specification, paragraph bridging pages 17 and 18.
12. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:
A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
14. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/25748 publication (published Sept 1995; PTO 1449).

The WO 95/25748 publication teaches purified fibrinogen (see entire document, page 17, line 24-25, in particular). "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a

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product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Thus, the reference teachings anticipate the claimed invention.

15. No claim is allowed.
16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Thursday from 9:00 a.m. to 6:30 p.m. and alternate Friday from 9:00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The IFW official Fax number is (571) 273-8300.
18. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Phuong Huynh/

Primary Examiner, Art Unit 1644

June 5, 2009